Retrovirology

BioMed Central

Poster presentation

Open Access

P15-08. Did unblinding affect HIV risk behaviour and risk perception in the HVTN503/Phambili study?

GE Gray*[1], L Bekker[2], G Churchyard[3], M Nchabeleng[4], K Mlisana[5], G de Bruyn[1], S Roux[2], M Mathebula[4], M Latka[3], T Bennie[4], B Metch[6], Z Moodie[6], M Allen[7], N Eaton[8] and J Kublin[8]

Address: [1]Perinatal HIV Research Unit, Soweto, South Africa, [2]Desmond Tutu HIV Foundation, Cape Town, South Africa, [3]Aurum Institute for Health Research, Cape Town, South Africa, [4]Medunsa HIV Clinical Research Unit (MeCRU), Tswane, South Africa, [5]Centre for the AIDS Programme for Research in South Africa (CAPRISA), Durban, South Africa, [6]Statistical Center for HIV/AIDS Research and Prevention, FHCRC, Seattle, WA, USA, [7]National Institute of Allergy and Infectious Diseases, NIH, Bethesda, MD USA and [8]HIV Vaccine Trials Network, Fred Hutchinson Cancer Research Center, Seattle, WA, USA

* Corresponding author

from AIDS Vaccine 2009
Paris, France. 19–22 October 2009

Published: 22 October 2009

Retrovirology 2009, **6**(Suppl 3):P209 doi:10.1186/1742-4690-6-S3-P209

This abstract is available from: http://www.retrovirology.com/content/6/S3/P209

Background

The HVTN 503/Phambili study, a phase IIB study of the Merck Ad-5 multiclade HIV vaccine, suspended enrollment and vaccinations following the results of the HVTN502/STEP study. Participants were notified of their treatment allocation and continue to be followed. We investigate the impact of study unblinding on HIV risk perception and behaviour.

Methods

Before suspension, 801 participants were enrolled. Data from all participants who had a post-treatment notification behaviour risk assessment (PTN-RA) were compared with the baseline RA. In addition an unblinding risk perception questionnaire was administered post-treatment notification (PTN).

Results

469 participants were eligible for risk behaviour analysis: median time between unblinding and administration of PTN-RA being 70 days (IQR: 39–108 days). At baseline, amongst men, there were no statistical differences in risk behaviour reported by treatment arm, and borderline differences in unprotected anal sex with a female partner (0% vaccinee vs. 2.9% placebo arm, p = 0.056), and a STI diagnosis (7.7% vaccinee vs. 2.2% placebo, p = 0.052). For women, there were no differences in risk behaviour by treatment arm at baseline. Post-treatment notification, risk behaviour change was similar for both sexes, with the pattern of change being similar in both arms. Between screening and the PTN-RA, significant reductions in number of sexual partners ($p < 0.001$), and unprotected sex ($p < 0.001$). were observed. 677 participants completed the unblinding risk perception questionnaire. In this assessment, men were more likely to report behaviour change (22.0%) than women (14.1%). Men reported increased condom use (64.6%), encouraging partner testing (51.2%) and reduced partner numbers (57.3%). More vaccinees (24.7%) as compared to placebo recipients (12.1%) agreed/strongly agreed that they were more likely to get HIV than most people ($p < 0.001$), which was attributed by the participant to receiving the vaccine.

Conclusion

Post-unblinding, vaccinees perceived being at increased risk of HIV, but risk behaviour reductions were noted irrespective of treatment allocation.